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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,743	07/10/2006	Christopher John Lawson	VOS0052/US	4138

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,743	Applicant(s) LAWSON ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority to EPO 0301550202 under 35 U.S.C. 119(a)-(d). The certified copy of the priority has been filed in the instant Application filed on January 06, 2006.

Claim Rejections - 35 USC § 112

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are drawn to a method of preparation of steroid modified trioses of general formula (Ia) and (Ib). The process step(s) recited in these claims is/are not seen to yield the intended products Ia or Ib. The claims have to recite all the essential steps leading to the intended products Ia or Ib. Claims 1-4 will be examined as drawn to a method for making the respective products that are recited in the claims.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is

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(a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation a sulfide group, and the claim also recites ethyl sulfide which is the narrower statement of the range/limitation. The same recitation is also seen in claims 4, 7 and 8.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (Carbohydrate Research, 2001, 331, 1-7).

Li teaches a triose modified with diosgenin (a steroid-same as R¹ being a steroid in instant formula VIIIa; page 2, left column, structural formula 15). The structure of the steroidal part shown in formula 1 at page 2, right column is diosgenin. In structure 15 of Li the sugar units at the left and at the bottom have a methyl group. This is the same as R² being a straight chain C₁ alkyl group in instant formula VIIIa. The sugar moiety to which the diosgenin is attached has pivaloyl group attached at the 3 and 6 positions in structure 15 of Li. This is the same as R⁵ being

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pivaloyl in instant formula VIIIa. The rest of the protecting groups in structure 15 of Li are benzoyl groups (Bz). This is the same as R⁴ being benzoyl in instant formula VIIIa. Structure 15 of Li et al meets the limitations of compound of general formula VIIIa of instant claim 25.

Li et al teach structural formula 2 (page 2, right column, Scheme 1). It is a steroid modified sugar that has a pivaloyl group at position 3 and 6 of the sugar moiety (same as R⁵ being pivaloyl in instant formula VIa). The dios moiety at the anomeric position is the steroid diosgenin (see steroid part in structural formula 1 of Li). Structure 2 of Li is seen to meet the limitations of a compound of general formula VIa of instant claim 27.

Li et al teach a steroid modified sugar having structural formula 1 (page 2, right column, Scheme 1). This meets the limitations of a compound of general formula Va of instant claim 29.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In the following rejection, claims 1-5 are rejected based on the product that is recited as being obtained after the recited steps.

Claim 1-5 and 10-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shahid (WO 03/018604).

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Shahid teaches the reaction of benzoyl protected glucopyranoside with the steroid solasidine to give product 8 (page 8, Step C). The benzoylated sugar 3 of Shahid that has a bromine at the anomeric carbon reads on instant formula IIa. This reads on instant claim 1 for the formation of instant formula IVa. Shahid's product 8 is next deprotected (benzoyl deprotection) to give product 9 (page 9; step D). This reads on instant claim 2 to obtain instant formula Va. The product from step D of Shahid is next reacted with pivaloyl chloride in the presence of pyridine to protect the hydroxyls selectively at 3 and 6 positions of the sugar moiety to give product 10 (page 10 Step E). This reads on instant claim 3, instant formula Via. Next product 10 from Step E of Shahid is reacted with two moles of rhamnose bromide in the presence of 4angstrom molecular sieves to yield the pivaloyl protected triose which is eventually deprotected to give the steroid modified triose (formula 12, page 12). This step reads on instant claims 4-5 and all the steps taught by Shahid above in the various steps also read on instant claims 10-18.

Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by Shahid (WO 03/018604).

Shahid teaches a steroid modified glucose (structural formula 8, page 8). The glucose is protected with benzoyl groups. This teaching meets the limitations of a compound of general formula IVa of instant claim 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 10-24, 26, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahid (WO 03/018604).

Shahid teaches the preparation of a steroid modified triose wherein the sugar moiety which bears the steroid part is glucose (as explained above). According to Shahid these compounds have potent antineoplastic properties (page 1, third paragraph). Shahid however, does not teach the preparation of a steroid modified triose wherein the sugar moiety bearing the steroid part is a galactosyl moiety as in instant formulas IIb and Ib. Shahid also does not teach

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a steroid modified triose of instant formula Ib starting with the sugar of formula IIb since the analogous glucosyl product of instant formula Ia is seen to be taught in the prior art.

One of skill in the art would be motivated to make the triose of instant formula Ib also since analogous products are taught to have potent antineoplastic activity. One of skill in the art would look for other similar products that may be more potent than the glucosyl analog and would want to make the galactosyl analog. One of skill in the art will also recognize that the same process steps could be used for the galactosyl analog containing only one rhamnose moiety. It is well within the skill level of the artisan to perform the same steps using other promoters, protecting groups, solvents.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahid (WO 03/018604) in view of Tamura (Trends in Glycoscience and Glycotechnology, 2001, 13(69), pages 65-88).

Shahid teaches the preparation of a steroid modified triose wherein the sugar moiety which bears the steroid part is glucose (as explained above). According to Shahid these compounds have potent antineoplastic properties (page 1, third paragraph). Shahid however, does not teach the preparation of a steroid modified triose wherein the sugar moiety bearing the steroid part is a galactosyl moiety as in instant formulas IIb and Ib and also the use of the selectively protected sugar of instant formula VIb. Shahid also does not teach the process steps for making the triose of formula Ib wherein the sugar attached to the steroid directly is galactose

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and the galsosyl part being attached to a glucose and a rhamnose. However, one of skill in the art will recognize that the process steps taught by Shahid are applicable to a galactosyl sugar and also that the process of Shahid can be modified to add a glucose and a rhamnose moiety to make the triose part.

Tamura, drawn to synthesis of glycosaminoglycans, teach the use of ketal protected sugar 40 (page 69) for building a sugar chain wherein the addition of a sugar moiety is directed at the unprotected hydroxyl at the 3 position to give structure 42 (page 68). Even though Tamura's teaching does not deal with the synthesis of a steroid modified triose as instantly claimed one of skill in the art will recognize from his teaching that a sugar moiety such as formula 40 of Tamura could be used to make a triose via the method as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a steroid modified triose of instant formula Ib starting with the sugar of formula IIb since the analogous glucosyl product of instant formula Ia is seen to be taught in the prior art.

One of skill in the art would be motivated to make the triose of instant formula Ib also since analogous products are taught to have potent antineoplastic activity. One of skill in the art would look for other similar products that may be more potent than the glucosyl analog and would want to make the galactosyl analog. One of skill in the art will also recognize that the same process steps could be used for the galactosyl analog containing only one rhamnose moiety by choice of the order of addition of the sugar moieties, based on the teachings of the prior art.

Conclusion

Claims 1-31 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit
1623

GK